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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,568	12/04/2003	Jon Elliot Adler	54072D3	5086

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EXAMINER	
BRANNOCK, MICHAEL T	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,568	ADLER ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *235-271* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *235-271* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 12/4/2003, have been entered in full. Claims 235-271 are pending and under examination in this Office Action.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see page 16 for example. Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable code. See MPEP 608.01.

Claim Objections

Claim 235 is objected to because of the following informalities: the phrase "based its" in claim 235(2) appears to be missing the word "on", i.e. "based on its".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 235-271 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 235, and dependent claims require a compound that "putatively" modulates or elicits human T1R1-associatied taste. It is unclear what limitations Applicant intends the world putatively to add to the claims, and nor is such explained in the specification. Thus, an artisan

could not be sure whether he or she was practicing or infringing on Applicant's claims. Similarly, the phrase "T1R1-associatied taste" renders the claims indefinite as there is no particular description provided in the specification which distinctly defines the phrase.

Claims 235 and 244 require that the nucleic acid hybridize under stringent conditions. The term stringent conditions is a relative term and encompasses conditions of varying degrees of stringency - such conditions determining the bounds of the claim. However, the art does not provide an unambiguous definition of the term "stringent conditions" and neither is such a definition given for the term in the specification which puts forth the metes and bounds of the claim Applicant is seeking protection for. The term appears to be defined only by way of example at page 30. It is suggested that the claim recite the actual conditions that applicant considers to be stringent, e.g., salt concentration and temperature conditions of incubations and washes.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 235-271 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to methods for identifying a compound that putatively modulates or elicits human T1R3-associated taste in a human subject, yet the specification has not taught what particularly human T1R3-associated taste is. The instant claims are directed to a

polypeptide of SEQ ID NO: 4 which is termed hT1R3. The specification asserts it is believed that T1R protein family members are components of the taste transduction pathway and may be involved in taste detection of sweet substances and/or other taste modalities but the specification does not teach what or how to measure "human T1R3-associated taste" as this phrase relates to the polypeptide of SEQ ID NO: 4. Additionally, claim 235 requires an embodiment that the identified compound modulate the specific binding of another compound that specifically binds to the polypeptide of SEQ ID NO: 4, yet no such compounds have been taught in the specification. The specification has not taught where to obtain such and it does not assert that any particular compound would have this property, yet an artisan would need such a compound to practice the invention. Furthermore, the claims require fragments of the polypeptide of SEQ ID NO: 4 or other polypeptides that are encoded by polynucleotides comprising as few as 500 polynucleotides of a polynucleotide SEQ ID NO: 2 or 20, the specification has not provided sufficient information so as to be able to know which of such polypeptides could be used in the claimed assays. Claim 244 requires only that the polypeptide be encoded by a polynucleotide that need only hybridize to a polynucleotide comprising as few as 500 polynucleotides of a polynucleotide SEQ ID NO: 15 or 16. The instant specification appears to simply suggest to the artisan that art-recognized procedures for screening GPCRs (e.g. pages 26 and 49-62) are sufficient to identify functional variants of SEQ ID NO: 4. However, Hoon *et al., Cell* 96(541-551)1999, report that "We have attempted to determine the ligand/tastant specificity of TR1 and TR2 using a variety of strategies but have been hampered by the difficulty of functionally expressing these molecules in heterologous system see col 1 of page 547". The art regarding T1R receptors, as exemplified by Hoon et al., recognizes the complexity, unpredictability, and

non-routine nature of the work involved in trying to assay functional T1R receptors. The instant specification has provided only general guidance to the skilled artisan -such guidance does not supply the artisan with the detailed methods one would need to possess in order to screen for functional variants. Further, the specification has offered no working example of such a screening method. While, it may be reasonable that the instant specification is enabling for variants that are at least 90% identical to SEQ ID NO: 4, see copending Application 09799629, the scope of the instant claims is vastly wider than such and does not appear to be supported by and adequate disclosure.

Due to the large quantity of experimentation necessary to generate the infinite number of variants recited in the claims and screen same for activity, the lack of direction/guidance presented in the specification regarding what particular activity is intended to be human T1R3-associated taste activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the nd the difficulties encountered in screening T1Rs, exemplifed by Hoon et al. and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Claims 235-270 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As set forth above, the claims require embodiments wherein the identified compound

modulate the specific binding of another compound that specifically binds to the polypeptide of SEQ ID NO: 4, yet no such specific binding compounds have been taught in the specification. The specification has not taught where to obtain such and it does not assert that any particular compound would have this property. Thus the one skilled in art would not recognize that Applicant was in possession of such compounds that are needed to practice the claimed methods.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 235-271 are provisionally rejected on the ground of nonstatutory double patenting over claims 235-286 of copending Application No. 10725081. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the instant claims are directed to binding assays whereas those of copending Application No. 10725081 recite "functional assays", however functional assays of this type are assays of binding, thus the instant claims would be covered by any patent granted in the 10725081 application.

Conclusion

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

September 28, 2006

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER